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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566

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EXAMINER

VANIK, DAVID L

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,103	SINGH ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Applicants' Remarks filed on 9/22/2005.

The Double Patenting rejections over copending Application No. 10/359,548 ('548) are hereby **maintained**. The 35 USC §102 rejections over US patent 5,945,457 ('457) and US patent 5,719,197 ('197) are hereby **withdrawn**. Additionally, the 35 USC §103 rejections over US patent 5,945,457 ('457) or US patent 5,719,197 ('197) are also hereby **withdrawn**.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-28, 38-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7-16, 21-61 of copending Application No. 10/359,548 ('548). Although the conflicting claims are not identical, they are not patentably distinct from each other because, like the instant application, co-pending application '548 teaches a composition comprising the following (Claims 1 and 55):

- 1) a water-swellaable, water-insoluble polymer,
- 2) a blend of a hydrophilic polymer with a complimentary oligomer,
- 3) an active agent or whitening agent,
- 4) a backing member (in the case of '548, a "release liner").

As stated above, '548 teaches a teeth whitening composition comprising a hydrogel (1-3) and a backing or release liner (4). The composition proposed by '548 can be used in a method for whitening teeth (Claims 53-61). The instant application uses the same (1) water-swellaable, water-insoluble polymers, (2) blend of a hydrophilic polymer with complimentary oligomers, (3) and whitening agents as set forth in the '548 claim set (Claims 1-3, 7-16, 21-40). The instant application and co-pending application '548 also use the same percentage of chemical components (see Claims 41-52 of '548). The polymer-based release liner of '548 is being interpreted as a "backing member." It should also be noted that several other references, such as US Patent 5,310,563 and 5,879,691, teach a teeth whitening system comprising a backing member. As such,

teeth whitening systems comprising a teeth whitening agent and a backing member are well known in the art.

With respect to the backing member, absent a clear showing of criticality, the determination of a backing member material is within the skill of the ordinary worker as part of the process of normal optimization.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed on 9/22/2005 have been fully considered but they are not persuasive. In response to the 6/17/2005 Non-Final Rejection, Applicant has asserted that the "backing member erosion limitation" present in the instant claim set is not obvious over the claims in copending Application No. 10/359,548 ('548). The examiner respectfully disagrees with this assertion.

Giving the instant claim set the broadest reasonable interpretation, it is the examiner's position that, given the claims of '548, it would have been obvious to one of ordinary skill in the art to formulate the "release liner" claimed by '548 (Claim 55) in such a manner that it erodes in a moist environment at a slower rate than the hydrogel. From a practical point of view, it is the examiner's position that one of ordinary skill in the art at the time the invention was made would have the motivation to ensure that the gel-based composition, such as a teeth whitening formula, erodes prior to the backing

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member. If the backing member would erode prior to the hydrogel or teeth whitening formulation, there would be nothing to hold said hydrogel or teeth whitening formulation in place. That is, from a practical point of view, the hydrogel tooth whitening formula would not be bound to a user's teeth if the backing member would erode prior to the hydrogel formulation. Given this, it is the examiner's position that one of ordinary skill in the art at the time the invention was made would have the motivation to formulate a release liner in such a manner that it would degrade at a slower rate than the hydrogel.

The motivation for one of ordinary skill in the art to formulate a teeth whitening composition wherein the hydrogel composition degrades at a faster rate than the backing member is also confirmed by US 5,879,691 ('691). Given the list of materials capable of being used as a backing member in '691, one would expect that the hydrogel would erode at a faster rate than the backing member (column 4, line 67 – column 5, line 12).

Applicant's arguments with respect to the rejection(s) of claim(s) 29-37 over US patent 5,945,457 ('457) and US patent 5,719,197 ('197) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a 35 USC § 112 rejection has been presented (see below).

NEW REJECTIONS:

The following is a list of new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a composition comprising (1) a hydrogel comprising a water swellable polymer and a blend of a hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that **erodes in a moist environment at a slower rate than the hydrogel**. Based on the instant disclosure, it is the examiner's position that Applicants do not describe this invention in such a manner that would enable one of ordinary skill in the art to practice this invention without undue burden. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

The breadth of claims: The instant claims 1-59 are directed to a composition comprising (1) a hydrogel comprising a water swellable polymer and a blend of a hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel. It is the examiner's position that this claim, as currently presented, is not supported by the instant specification.

The nature of the invention: Like the instant claim set, the instant invention is directed to a composition comprising (1) a hydrogel comprising a water swellable polymer and a blend of a hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel. As set forth on pages 11-24, the hydrogel-based composition can comprise a multitude of polymers and active agents. Although Applicant discloses numerous polymers and active agents, there is nothing in the specification suggesting that any combination of water-swallowable polymers (pages 13-15), hydrophilic polymers (pages 16-17), complimentary oligomers (pages 18-20), and active agents (pages 20-26) is capable of eroding at a slower rate than the hydrogel. Moreover, since the backing member can be the same polymer as the hydrogel, one of skill in the art would be faced with undue experimentation in formulating a hydrogel/backing member composition wherein the

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backing member erodes at a slower rate than the hydrogel. This problem is identified by Applicant on page 30, paragraph 00114. Specifically, the situation where Eudragit is used as both the water-swellaable polymer and the backing member is probed.

However, this section of the disclosure does not address the situation where the backing member and water-swellaable polymers are compounds other than Eudragit. Additionally, paragraph 00114 does not account for the other elements of the hydrogel composition, such as the hydrophilic polymer, complimentary oligomer, and active agent.

Since, as set forth in the instant Claim 1, the water-swellaable-polymer and backing member are not specifically defined, one of skill in the art would not have the ability to formulate a composition comprising any hydrogel together with any polymeric backing member wherein said backing member is capable of eroding at a slower rate than said hydrogel.

The amount of direction provided by the inventor: There is nothing in the specification that would indicate that the current invention is capable of working with any water-swellaable polymers, hydrophilic polymers with complimentary oligomers, active agents, and backing members. Moreover, viewed in light of the instant specification, one of ordinary skill in the art would not have the ability to produce hydrogel compositions and backing members wherein said backing member erodes at a slower rate than said hydrogel. There is nothing in the instant specification that details the time it takes for a given hydrogel composition to erode. Given the number of possible water-

swellable polymers, hydrophilic polymers with complimentary oligomers, and active agents disclosed in the instant specification, one of ordinary skill in the art would not have the ability to formulate a hydrogel-based composition capable of eroding in a set amount of time. The same principle applies to the backing member. That is, there are no teachings in the instant specification that indicate that a particular backing member is capable of eroding in a moist environment in a specified amount of time.

In short, guidance for preparing a composition comprising a (1) a hydrogel comprising a water swellable polymer and a blend of a hydrophilic polymer with a complimentary oligomer capable of hydrogen bonding to said hydrophilic polymer and (2) a backing member comprised of a polymer composition that **erodes in a moist environment at a slower rate than the hydrogel** is not provided in the specification. As a result, one of ordinary skill in the art would have to revert to trial and error experimentation in order to practice the invention commensurate in scope with the instant claim set. With respect to the instant composition, there is a substantial gap between a composition comprising a specific combination of hydrogel and backing member agents and one comprising any and all hydrogel and backing member agents. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap.

The presence or absence of working examples: There are three examples set forth in the instant specification, none of which teach the erosion times of hydrogels and backing members in moist environments. As such, based on the instant disclosure, one

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of ordinary skill in the art would not have the ability to make/use the invention commensurate in scope with the claims without undue experimentation.

The quantity of experimentation: In the instant case, there is a substantial gap between a composition comprising a specific combination of hydrogel and backing member agents and one comprising any and all hydrogel and backing member agents. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art to bridge this gap. In order to utilize the invention as claimed, the skilled artisan would be presented with an unpredictable amount of experimentation. The instant disclosure is broad and generic. It is not clear what specific embodiments would be required in order for one of ordinary skill in the art at the time the invention was made to practice the instant invention commensurate in scope with the claims.

The relative skill of those in the art: the skill of one of ordinary skill in the art is very high, e.g., Ph.D. and M.D. level technology.

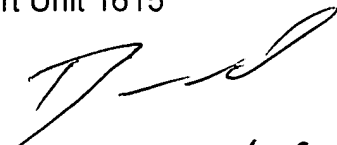
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

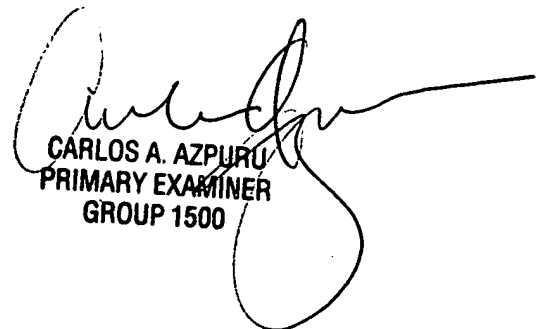
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1615



2/15/06



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